

### **REMARKS**

Claims 1-5, 7-37 and 41-42 are therefore pending. Claim 19 has been amended to delete the target sites of the intralaminar thalamic nuclei and the dorsomedial nucleus of the thalamus. Applicants reserve the right to prosecute this subject matter in an application that claims priority to the present application.

### **INFORMATION DISCLOSURE STATEMENT**

In the previous response, a copy of Rezai et al., “Deep Brain Stimulation for Chronic Pain,” in *Surgical Management of Pain*, Chapt. 44, pp. 565-576 (2002) was submitted (such reference having been cited in an IDS filed on 7/23/04). In the previous response, Applicants requested that the Form PTO-1449 included with the previously filed IDS be marked to confirm the Examiner’s consideration of this reference. Such initialed IDS has still not been received and Applicants therefore submit this request again.

### **Rejection of Claims 1, 4, 19, 20, 22, 24, and 36 Under 35 U.S.C. 102(e) by Baudino**

Claims 1, 4, 19, 20, 22, 24 and 36 stand rejected as being allegedly anticipated by U.S. Patent No. 6,353,762 to Baudino (“Baudino”). Applicants traverse this rejection.

Baudino describes devices and techniques for selectively affecting and adjusting a volume of neural tissue in the brain and other parts of the nervous system (See Abstract in Certificate of Correction). Baudino is not directed to methods of affecting specific conditions by modulating specific target sites in the brain.

It is true that Baudino mentions chronic pain in passing and it is true that Baudino mentions some of the sites recited in the present claims but it does so in a manner that does not amount to a teaching of affecting chronic pain by stimulating those mentioned sites. Specifically, Baudino refers to chronic pain separately from any sites recited by the present claims such as the anterior limb of the internal capsule, the dorsal medial nucleus of the thalamus, and the anterior nucleus of the thalamus (which are the sites pointed out by the Examiner<sup>1</sup>). Further, these sites are listed among a laundry list of other sites and there is no

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<sup>1</sup> It should be noted that the Examiner also states that Baudino describes the lateral hypothalamus and the ventral pallidum as recited by claim 19. However, this is not what Baudino mentions. Baudino mentions the internal and external pallidum but not specifically the ventral pallidum. Further, Baudino mentions the hypothalamus but not the lateral hypothalamus.

disclosed connection between any of these sites and any disclosed conditions or disease states that may be treated by stimulation of these sites.

With respect to chronic pain, Baudino only states:

“It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain, or to control movements.”

Col. 9, lines 21-24. Such a passing comment provides absolutely no target sites for treating chronic pain, let alone detecting a bodily activity associated with chronic pain to adjust a stimulation signal sent to a target site as recited by claims 1 and 19.<sup>2</sup> In fact, such a statement does not provide anything over the art. Neuromodulation of “particular neural tissue elements” to provide “treatment of a [certain] neurological disorder[s]. . . chronic pain or to control movements” has been known. What is not known is the specific target sites identified by Applicants in claims 1 and 19 to treat chronic pain. In this passage, Baudino does not provide what the “particular neural tissue elements” are for treating chronic pain.

The Examiner relies on a completely separate paragraph of Baudino that describes where the “present invention” can be used to deliver therapy to argue that Baudino teaches treating chronic pain by stimulating these sites. However, the paragraph identifies no specific therapies (i.e. specific conditions are diseases that are treated by modulation of the listed sites). It simply states:

The present invention *may* be used to deliver treatment therapy to any number of sites in the brain. Particular sites within the brain include, for example, the subthalamic nucleus (STN), the peduncular pontine nucleus (PPN), the caudate or putamen, the internal and external pallidum, the cingulum, the anterior limb of the internal capsule, the anterior nucleus (AN), the centremedian (CM), the dorsal medial nucleus and other nuclei of the thalamus, the hippocampus and other structures in the temporal lobe, the hypothalamus and other structures of the diencephalon, the pons, the medulla, the cortex, the cerebellum, the lateral geniculate body, and the medial geniculate body. The desired configuration of the electrodes would depend upon the structure of the portion of the brain to be stimulated or infused and the angle of introduction of the deep brain cannula.

Col. 9, line 61 to col. 10, line 9. It should first be noted that these sites (i.e. “the cortex,” “the diencephalon” (which covers the thalamus), “other nuclei of the thalamus,” “the hippocampus,”

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<sup>2</sup> The Examiner cites to col. 2, lines 54-62 of Baudino for the alleged teaching of detecting a bodily activity associated with chronic pain. It should be noted that this cited passage of Baudino only refers to “pain” and not chronic pain, which is recited in the present claims.

“the hypothalamus,” “the temporal lobe,” “the cerebellum,”) cover the vast majority of the brain at least at a general level. Further, these sites are mentioned in conjunction with configuration changes of the device described in Baudino and are certainly not linked to any specific disorders, let alone chronic pain. Baudino couches this list of sites in terms of delivering “treatment therapy” but there is no more specificity regarding particular indications or disease states than that. And Applicants emphasize that this laundry list of target sites cannot be interpreted to be target sites for treating chronic pain since Baudino never states that it provides methods for treating chronic pain, let alone methods of treating chronic pain by modulating the above-referenced sites. As stated above, Baudino describes devices and techniques for selectively affecting and adjusting a volume of neural tissue in the brain and other parts of the nervous system (See Abstract in Certificate of Correction). Baudino is not directed to methods of affecting specific conditions by modulating specific target sites in the brain. The passage cited by the Examiner: “[i]t is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain, or to control movements” does not amount to a teaching of treating chronic pain by any particular methodology. If this passage is read as disclosing a method of treating chronic pain, then it is must be read to disclose a method of treating a “neurological disorder” (which is also mentioned in this passage) and which covers hundreds of medical conditions for which Baudino certainly cannot be considered to be enabled. This is particularly true since the sites referenced by Baudino cover virtually ever site in the brain so based on the Examiner’s logic, Baudino teaches treating a neurological disorder (again which covers hundreds of conditions) by stimulating virtually any site in the brain. This simply cannot be correct since it is unreasonable to think that Baudino is enabled for such treatment methods.

In fact, this lack of any link to chronic pain and the sites mentioned in the above paragraph, can be seen by the statement in Baudino that immediately follows the sentence that mentions chronic pain. Specifically, right after mentioning chronic pain, Baudino states that “often, nearby groups of neurons or axons, e.g., the optic nerve, internal capsule. . . are in special orientations and groupings. It may be advantageous to avoid affecting them. . . ” (Col. 9, lines 24-25). While it is true as indicated by the Examiner that Baudino also states that these sites can be deliberately affected, the point is that Baudino does describe avoiding a site that is clearly claimed by Applicants as being a site that can be stimulated to treat chronic pain. This passage is

being pointed to to buttress Applicants' position that Baudino does not contemplate treating chronic pain by modulating the particular sites recited in the present claims since Baudino states that the internal capsule may or may not be stimulated.

Applicants are simply stating that Baudino must be taken in its entirety and bits and pieces cannot be relied upon to support a position that Baudino anticipates the present claims. Just because "chronic pain" and any of the sites recited in the claims are in the same reference does not mean that the reference teaches the subject matter of the recited claims. (See In re Arkley, 455 F.2d 586, 587, 172 USPQ 524 (CCPA 1972) ("the reference ... must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference."); Sandisk Corp. v. Lexar Media, Inc., 91 F. Supp.2d 1327, 1336 (N.D. Calif. 2000) ("Unless all the elements are found in a single piece of prior art in exactly the same situation and united the same way to perform the identical function, there is no anticipation.").

Further, recent caselaw emphasizes the impropriety of the Examiner's analysis of pasting bits and pieces of Baudino's disclosure to argue that Baudino teaches treating chronic pain by modulating the particular sites. Specifically, Net Moneyin, Inc. vs. Verisign, Inc. et al. (No. 2007-1565. Fed. Circ. 2008). In this case, the Federal Circuit specifically held that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed, and thus cannot anticipate under 35 U.S.C. 102. Applicants believe that Baudino does not even clearly provide for a method of treating chronic pain, let alone a method of treating chronic pain by modulating the specifically claimed sites. Even if Baudino provides for a method of treating chronic pain, the treatment sites referenced by the Examiner and a method of treating chronic pain are not "arranged or combined in the same way as recited in the claims." In other words, Baudino does not clearly link treating chronic pain with the sites referred to later in the Baudino patent.

Again, the neurological sites are mentioned with respect to the desired configuration of the electrode, which is stated as depending upon the structure of the portion of the brain to be stimulated or infused and the angle of introduction of the deep brain cannula. This mention of these neurological sites relative to certain electrode configurations makes sense since, as

mentioned before, Baudino is directed to devices and techniques for “activation of neurons.” The Examiner states that “Applicants does not claim any specific electrode configuration other than ‘implanting a stimulator in a target site of the brain.’” Applicants do not understand the relevance of this statement. What Applicants are stating is that the list of neurological sites listed by Baudino is not mentioned with respect to treating particular disorders but with respect to the fact that the “desired configuration of the electrodes would depend upon the structure of the portion of the brain to be stimulated.” Indeed the quoted statement regarding the electrode configuration is made in Baudino at the end of the paragraph listing the neurological sites. Applicants are simply asserting that the mention of these neurological sites must be taken in context with the rest of Baudino which is directed to devices and techniques (including electrode configuration) for activating neurons and that Baudino is simply stating that its devices can be used in certain sites of the nervous system and that the configuration of the electrodes of such devices will depend on which sites the electrodes are in. Baudino is not teaching methods of treating particular disorders by modulating these listed sites (more information would be needed to enable such methods including the particular sites within Baudino’s list associated with the particular disorders to be treated, stimulation parameters for the particular disorders, etc. None of that is provided by Baudino).

Further, Baudino does not describe the express stimulation parameters recited by claims 1 and 19 and therefore does not teach an express limitation of the claims. For at least these reasons, Applicants submit that Baudino does not anticipate claims 1 and 19 (and all claims that depend therefrom) and Applicants request withdrawal of this rejection.

### **Rejection of Claim 37 Under 35 U.S.C. 102(b) By MacDonald**

Claim 37 stands rejected as being allegedly anticipated by U.S. Patent No. 5,776,170 to MacDonald (“MacDonald”). Applicants traverse this rejection. Claim 37 recites “implanting a stimulator in communication with a pain circuitry target site.” As described in the specification, “by ‘pain circuitry target site’ is meant either a cerebral target site or a deep brain target site, as described by the present invention.” (see paragraph 15). The specification then describes the specific cerebral target sites and the specific deep brain target sites and provides the stereotactic coordinates for these sites (See paragraph 15 and 17). MacDonald does not describe these sites. In fact, when describing implanting electrodes, as admitted and quoted by the Examiner,

MacDonald refers to implanting the electrodes in the body either in “tissues near the spine or within the spinal cord itself. (See col. 8, lines 55-57). Obviously, tissues near the spine or the spinal cord themselves are not the deep brain and cerebral target sites claimed in claim 37 by recitation of the limitation a “pain circuitry target site,” which is specifically defined in the present specification. With respect to new claims 41 and 42, MacDonald certainly does not describe implanting any electrodes in the cortical or deep brain regions of the brain as recited by claims 41 and 42.

Furthermore, there is absolutely no mention in MacDonald of “providing a stimulation signal to the stimulator to stimulate the synthesis or release of an endogenous opioid to affect chronic pain,” which is an express limitation of claim 37. Further, there is no reason to believe this is a necessary result of the teachings of MacDonald particularly since MacDonald does not describe stimulating a “pain circuitry target site” as that term is defined by the present invention.

For at least these reasons, Applicants submit that claim 37 and all claims that depend therefrom are not anticipated by MacDonald and Applicants request withdrawal of this rejection.

**Rejection of Claims 19, 21, 26-31 and 33-35 Under 35 U.S.C. 103 by Baudino in view of Baudino**

Claims 19, 21, 26-31 and 33-35 stand rejected for being allegedly anticipated by Baudino in view of U.S. Patent No. 5,938,688 to Schiff (“Schiff”). The only site in the brain that Schiff describes placing an electrode in is the intralaminar nuclei. Applicants have deleted this from the Markush group of claim 19. Since Baudino does not describe this site, Applicants submit that neither Schiff nor Baudino describe each and every element of the claims.

Further, there is no motivation to implant an electrode in the sites recited by claim 19. Schiff is clearly and strongly directed to placing an electrode in the ILN and not in any other sites of the brain. As such, one skilled in the art would not be motivated to place the electrode anywhere else to treat chronic pain. For at least these reasons, Applicants submit that claim 19 and all claims that depend therefrom are not anticipated by Baudino in view of Schiff.

**Rejection of Claims 1-36 Under 35 U.S.C. 103 by Baudino**

Claims 1-36 stand rejected under 35 U.S.C. 103 as being allegedly rendered obvious by Baudino. In this rejection, the Examiner addressed the sites that are not specifically listed in Baudino's laundry list of sites. According to the Examiner, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to try to stimulate these other cortical and deep brain sites in the brain since these references teach that it is known to stimulate cortical sites and deep brain sites to affect chronic pain and there are a finite number of cortical sites and deep brain sites and determining the best site to stimulate in the brain would be obvious to one having ordinary skill in the art.

Of course there are a finite number of cortical and deep brain sites but given that the brain consists of either cortical or deep brain sites, the Examiner is essentially saying that if Baudino describes stimulating certain specific site in the brain then one skilled in the art would be motivated to stimulate any other site in the brain. That is simply not true. One skilled in the art would need to have some reason to stimulate the sites pointed out by the Examiner that are not described by Baudino. The Examiner has shown no connection between the sites recited by Baudino and those recited in claims 1 and 19 and has shown no link between those sites recited in claims 1 and 19 and chronic pain (and even if he had done so that does not mean that stimulation of those sites will result in any therapeutic benefit). Based on the Examiner's logic, if a reference describes stimulating one brain site for treating a certain disorder (and again, Applicants are not conceding that Baudino describes treating any particular disorders), then it would be obvious to stimulate any other site in the brain to treat the same disorder.

Moreover, as evidenced by the attached declaration which was submitted in another case, even if two sites are within the same neural pathway, that does not mean that stimulating both sites will have the same therapeutic effect. For example, treatment of Parkinson's disease has been accomplished in the past with deep brain stimulation of the globus pallidus, the subthalamic nucleus, and the thalamus. Although these three structures are part of the same circuit, the effects of stimulation on each structure are not the same. For example, stimulation of the subthalamic nucleus and globus pallidum can alleviate rigidity and bradykinesia but stimulation of the thalamus has no recognizable benefit on these two conditions.

Therefore, even if the sites indicated by the Examiner that are not listed by Baudino were part of the same circuitry as the sites that are listed by Baudino, that does not mean that all such sites will have the same effect on a condition like chronic pain.

For at least these reasons, Applicants submit that claims 1-36 are not rendered obvious by Baudino.

**Rejection of Claims 41 and 42 Under 35 U.S.C. 103(a) by MacDonald and further in view of Baudino or Schiff**

Claims 41 and 42 stand rejected as being allegedly rendered obvious by MacDonald. Applicants traverse this rejection. As stated above, Baudino does not describe treating pain by stimulating any particular sites. Schiff only mentions the intralaminar nuclei. Thus none of the references either alone or in combination describe all the elements of claims 41 and 42.

Further, there is no description of “providing a stimulation signal to the stimulator to stimulate the synthesis or release of an endogenous opoid to affect chronic pain” in a patient in need thereof and the Examiner has made no argument as to why such opoids would be inherently released or synthesized by the methods of MacDonald, Schiff and/or Baudino.

**CONCLUSION**

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants’ representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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